

In re Application of: Ding *et al.*

Serial No.: 10/022,607

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For: DRUG RELEASE COATED STENT

PENDING CLAIMS

1. An expandable stent for implantation in a patient comprising:
 - (a) a tubular metal body having open ends and a sidewall structure having openings therein, wherein said sidewall structure is prefabricated; and
 - (b) a coating disposed on a surface of said prefabricated sidewall structure, said coating comprising a hydrophobic biostable elastomeric material and a biologically active material, wherein said coating continuously conforms to said structure in a manner that preserves said openings.
2. The stent of claim 1, wherein said coating is about 20 to about 200 μm in thickness.
3. The stent of claim 1, wherein the coating continuously conforms to the structure in a manner that preserves said openings when the stent expanded.
4. The stent of claim 1, wherein the coating is applied to the surface of the sidewall structure by spraying a coating composition comprising a mixture of finely divided biologically active species and an about 4 to 6 w/v % dispersion of uncured hydrophobic biostable elastomeric material in a solvent.
5. The stent of claim 1, wherein said coating is about 75 to about 200 μm in thickness.
6. The stent of claim 1, wherein said coating is applied with said stent fully expanded.

7. The stent of claim 1, wherein said coating is applied with said stent rotated.
8. The stent of claim 1, wherein said stent is a self-expandable stent.
9. The stent of claim 1, wherein the metal is selected from the group consisting of stainless steel, titanium alloys, tantalum, and cobalt-chrome alloys.
10. The stent of claim 1, wherein the biostable elastomeric material is selected from the group consisting of polysiloxanes, polyurethanes, thermoplastic elastomers, ethylene vinyl acetate copolymers, polyolefin elastomers, ethylene-propylene terpolymer rubbers and combinations thereof.
11. The stent of claim 1, wherein the biostable elastomeric material is a polysiloxane and wherein said biologically active species is selected from the group consisting of heparin and dexamethasone.
12. An expandable stent for implantation in a patient comprising:
 - (a) a tubular metal body having open ends and a sidewall structure having openings therein, wherein said sidewall structure is prefabricated; and
 - (b) a coating on a surface of said prefabricated sidewall structure, said coating comprising a hydrophobic biostable elastomeric material and a biologically active material, wherein said openings are substantially free of webbing.
13. The stent of claim 12, wherein said coating is about 20 to about 200 μm in thickness.
14. The stent of claim 12, wherein said openings are substantially in the shape of a parallelogram with first and third sides that are substantially parallel and second and fourth sides that are substantially parallel, and wherein said openings are substantially free of webbing such that any imaginary line extended orthogonally from said first side to said third side does not intersect said coating extending between said second and fourth sides.
15. The stent of claim 12, wherein the coating is applied to the surface of the sidewall structure by spraying a coating composition comprising a mixture of finely divided

biologically active species and an about 4 to 6 w/v % dispersion of uncured hydrophobic biostable elastomeric material in a solvent.

16. The stent of claim 12, wherein said coating is about 75 to about 200 μm in thickness.

17. The stent of claim 12, wherein said coating is applied with said stent fully expanded.

18. The stent of claim 12, wherein said coating is applied with said stent rotated.

19. The stent of claim 12, wherein said stent is a self-expandable stent.

20. The stent of claim 12, wherein the metal is selected from the group consisting of stainless steel, titanium alloys, tantalum, and cobalt-chrome alloys.

21. The stent of claim 12, wherein the biostable elastomeric material is selected from the group consisting of polysiloxanes, polyurethanes, thermoplastic elastomers, ethylene vinyl acetate copolymers, polyolefin elastomers, ethylene-propylene terpolymer rubbers and combinations thereof.

22. The stent of claim 12, wherein the biostable elastomeric material is a polysiloxane and wherein said biologically active material is selected from the group consisting of heparin and dexamethasone.

23. A self-expandable stent for implantation in a patient comprising a tubular metal body having open ends and a sidewall structure having openings therein, wherein said sidewall structure is prefabricated, and a coating of about 75 to about 200 μm in thickness on a surface of said prefabricated sidewall structure, said coating comprising a biologically active material and a hydrophobic biostable elastomeric material selected from the group consisting of polysiloxanes, polyurethanes, thermoplastic elastomers, ethylene vinyl acetate copolymers, polyolefin elastomers, ethylene-propylene terpolymer rubbers and combinations thereof, wherein said coating continuously conforms to said structure in a manner that preserves said openings.

24. The stent of claim 23, wherein the coating continuously conforms to the structure in a manner that the openings are substantially free of webbing.

25. The stent of claim 23, wherein the coating continuously conforms to the structure in a manner that preserves the openings when the stent expanded.

26. The stent of claim 23, wherein said coating is applied to the surface of the sidewall structure while the stent is fully expanded and rotated by spraying, with an air brush with its pressure adjusted to from about 15 to about 25 psi, a coating composition comprising a mixture of finely divided biologically active species and a dispersion of uncured hydrophobic biostable elastomeric material in a solvent and then cured.

27. The stent of claim 23, wherein the stent is rotated at the speeds in the range of about 30 to about 50 rpm.

28. The stent of claim 23, wherein the coating composition is sprayed at a spray nozzle flow rate in the range of about 4 to about 10 ml.

29. The stent of claim 23, wherein the coating comprises more than one coating layer.